

**REMARKS**

In response to the Office Action mailed October 10, 2006, Applicant respectfully requests the Examiner to reconsider the above-captioned patent application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 2, 5, 11, 13-14, 17, 20, 23, 31-39 and 42 have been amended. New claims 43-49 have been added. Figures 8 and 14 have been modified with new Figures 14B and 14C added and the specification has been changed accordingly.

In the Office Action mailed October 10, 2006, the Examiner disposed of the claims as follows:

Applicant thanks the examiner for the allowance of Claims 1, 3, 4 and 30.

The Examiner objected to the drawings.

Claims 17-22 and 24 were objected to.

Claims 2, 5-16, 23, 25-29 and 31-42 were rejected.

**I. 37 C.F.R. § 1.83(a) Objections**

The Examiner objected to the drawings under 37 C.F.R. 1.83(a) because the Examiner asserted that pre-biasing devices that are not springs and different sensors are claimed but not shown in the drawings. The drawings have been revised to reflect these aspects of the claimed invention. Accordingly, Figure 8 has been modified showing item 120 as a graphical drawing symbol (a labeled rectangular box) since the applicant considers a detailed illustration is not essential for a proper understanding of the invention under 37 C.F.R. 1.83(a).

Figure 14 has been modified by calling original Figure 14 as now Figure 14A and adding Figures 14B and 14C. Accordingly corrections to the specification have been made to incorporate these changes.

**II. Claims Objected To**

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The Examiner objected to claims 17-22 and 24, but indicated that these claims would be allowable if rewritten in independent form to include all the limitations of their base claim(s). Applicant has so rewritten Claims 17 and 20 in independent form, and therefore respectfully submits that amended claims 17 and 20 are in condition for allowance. Applicant further submits that Claims 18 and 21-24 are also in condition for allowance over the prior art, by virtue of their dependence from an allowable base claim, as well as their recitation of further novel and unobvious combination of features. Claim 19 depends from Claim 5. In view of the amendment of Claim 5 and the allowability thereof discussed below, Claim 19 has not been rewritten but is allowable at least for the same reasons that Claim 5 is allowable.

### III. 35 U.S.C. § 112 ¶2 Rejections

The Examiner rejected claims 2, 11, 13, 14, 23, 31-39 and 42 under 35 U.S.C. § 112 ¶2 as indefinite for failing to particularly point out and distinctly claim the subject matter the applicant regards as the invention. The Applicant does not agree with the propriety of these rejections and traverses the same. Nonetheless and to expedite the prosecution of the pending applications, these rejections have been addressed as follows:

Regarding claim 2, the Examiner asserted that a sleeve cannot surround the claimed apparatus if it is claimed as a component of the apparatus. The wording of this claim has been amended to clarify that the sleeve surrounds the claimed apparatus and is not necessarily a component of the apparatus.

Regarding claims 11 and 13, 14 and 23, the Examiner states that it is not clear if the sheath (claims 11 and 13), the one or more rubber bands (claim 13) or the delivery device (claim 23) is actually being recited in the respective claims. The wording of claims 11-13 have been amended to clarify that the sheath is being recited. Likewise the wording of claim 14 has been amended to clarify that the rubber bands are being recited. Furthermore the wording of claim 23 has been amended to clarify that the treatment delivery device is being recited.

Regarding claims 31-39 and 42, the Examiner states that the preamble should be corrected to "apparatus" instead of "device". Applicant has amended claims 31-39 and 42 to address the Examiner's objections.

#### IV. 35 U.S.C. § 102 Rejections

The Examiner rejected claims 5-8, 10, 11, 25 and 41 under 35 U.S.C § 102(b) as being anticipated by Voda, USP 5,462,561. In response Claim 5 has been amended in a manner which is believed to obviate the Examiner's rejection. In particular, Claim 5 has been amended to recite (emphasis added):

5. An apparatus comprising:

a central member adapted to permit the passage of a penetrating member adapted to penetrate tissue; and

a first substantially straight leg member having first and second ends connected to a distal portion of said central member at only one end,

wherein said first substantially straight leg member is adapted to curl radially to produce an increase in a distal radius of said apparatus,

and wherein said increase is adapted to restrain motion of said apparatus in a proximal direction.

In contrast to the amended claim, in Voda, as shown in Figures 19-21, the arms have a pre-set curvilinear shape inside the passageway 84. Thus the arms are at least partially pre-curved having one radius and then spring out (column 9, lines 30 and 31) to an enlarged radius once outside the passageway. Nothing in Voda teaches that the arms have a substantially straight leg member that is then adapted to curl radially. The legs of the present invention are substantially straight inside the central member and then curl outwardly either by active manipulation or by self expansion.

In view of these distinctions, Applicant respectfully submits that amended Claim 5 is in a condition for allowance over the prior art. Applicant further submits that Claims 6-8, 10, 11, 25 and 41 are also in condition for allowance over the prior art, by virtue of their dependence from an allowable base claim, as well as their recitation of further novel and unobvious combination of features.

The Examiner rejected claims 5-7, 10, 16, 25 and 41 under 35 U.S.C § 102(b) as being anticipated by Erb, et al., USP 6,436,119. In response Claim 5 has been amended in a manner which is believed to obviate the Examiner's rejection. In particular, Claim 5 has been amended as shown above to recite that the leg member curls outwardly to expand the effective diameter.

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In contrast to the amended claim, in Erb, as shown in Figures 6A-6E and Figure 10, The dilator the first and second arms 60 and 62 are displaced radially in a linear manner in a direction shown in Figure 2B, substantially orthogonal to the axis of the device without any change in configuration along the length of said arms. This type of expansion spreads apart the tissue, dilating a larger opening in the tissue. In fact the purpose of the dilator described by Erb is to create an opening in tissue that is larger than the original puncture size – hence the name dilator. The applicant's invention is not a dilator and is configured to enter tissue causing at least an initial opening and then actively or passively curl the arms outwardly whereby the configuration of the arms changes. The configuration of the arms is intended to provide an anchor that is larger than the initial puncture opening.

In view of these distinctions, Applicant respectfully submits that amended Claim 5 is in a condition for allowance over the prior art. Applicant further submits that Claims 6-7, 10, 16, 25 and 41 are also in condition for allowance over the prior art, by virtue of their dependence from an allowable base claim, as well as their recitation of further novel and unobvious combination of features.

Finally, the Examiner rejected claims 5-13, 15, 16, 25-29, 40 and 41 under 35 U.S.C § 102(e) as being anticipated by Frazier, et al., USP 6,746,472. In response Claims 5 and 26 have been amended in a manner which is believed to obviate the Examiner's rejection. In particular, Claim 5 has been amended as shown above to recite that the "leg member has first and second ends connected to a distal portion of said central member at only one end. In Figures 15, Frazier illustrates several barb configurations whereby the barb may be formed from a sheet or hollow tube. The forming methods referenced (column 14, line 14) and shown in Figures A&B describe one or more barbs 94 that are stamped or cut from flat sheet stock. This describes a static configuration that does not teach that these initially straight barbs curl radially outwardly once the apparatus is positioned inside tissue. Figures 15 D-G illustrate a central member with outwardly curled barbs 94 but these are pre-formed in the central member and are not shaped in situ (ref a hypotube or a punched and rolled sheet stock, lines 26-29 and 37-45 column 14). Furthermore, in these illustrations, Frazier does not recite any structure that could be used to actively form the barbs as shown out of the rolled tube after the apparatus is placed in a position for deployment. Therefore it must be assumed that the barbs are integrally pre-formed unlike the apparatus of the applicant.

The apparatus of Figures 16-18 as shown in Frazier shows 1<sup>st</sup> and 2<sup>nd</sup> proximal and distal projections 136, 137, 146, 147 that can be made to expand radially in response to an axial shortening of the tubular body 92. These projections are not curled radially outwardly but are formed from two slanted straight sections with a crease or hinge point in the middle. These projections do not have first and second ends that are connected to a distal portion of the tubular body at only one end but rather are coupled to the tubular body at both ends. Also the projections can only be formed in response to axial shortening of the anchor (column 15 line 12 and column 15 line 23) whereas the Applicant's design may be shortened in the absence of axial shortening and by utilizing other members.

In view of these distinctions, Applicant respectfully submits that amended Claim 5 is in a condition for allowance over the prior art. Applicant further submits that Claims 6-13, 15, 16, 25, 27-29 and 41 are also in condition for allowance over the prior art, by virtue of their dependence from an allowable base claim, as well as their recitation of further novel and unobvious combination of features.

Finally, the Examiner rejected Claim 40 as also being anticipated by Frazier but since Claim 40 depends from a previously allowed independent Claim 1, applicant submits that Claim 40 should also be allowed by virtue of its dependence from an allowable base claim, as well as recitation of further novel and unobvious features.

#### V. New Claims

Submitted herein are new Claims 43-49, comprising a new device claim with four dependent claims and a new method claim with one dependent claim. Applicant submits that these claims are believed to be allowable over the prior art of record, due to their recitation of further novel and unobvious combination of features.

#### VI. Authorization of Agent

Applicant is submitting a signed Authorization of Agent record to effectively revoke any previous Powers of Attorney in the subject application and authorize Scott Evans to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected herewith. The Agent respectfully requests that this Authorization of Agent be recorded and that herewith the Agent's Customer Number 45, 245 be associated with this application.

**CONCLUSION**

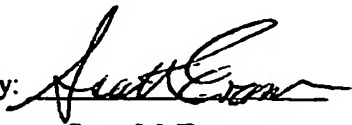
Applicant has properly and fully addressed each of the Examiner's grounds for rejection and objection. Applicant respectfully submits that all claims of the present application are now in condition for allowance. Accordingly, issuance of a Notice of Allowance is most earnestly solicited. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments, deletions and cancellations have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments, deletions and cancellations are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if issues require clarification, the Examiner is respectfully requested to call the Applicant's agent, Scott M. Evans at (714) 307-9290 to resolve such issue(s) promptly.

Respectfully submitted,

Dated: Feb 16, 2007

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